IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	:	Jo Klaveness et al.
Application No.	:	10/573,606
Filing Date	:	March 28, 2006
Art Unit	:	6864
Title	:	Optical Imaging of Colorectal Cancer
Docket No.	:	PN0368

Mail Stop Appeal Brief – Patents
Commissioner for Patents
PO Box 1450
Alexandria VA 22313-1450

APPEAL BRIEF

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I. REAL PARTY IN INTEREST

The real party in interest in this Appeal is GE Healthcare, Inc., a part of General Electric "GE".

II. RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences related to the instant appeal.

III. STATUS OF CLAIMS

Claims 15-18, 20, 21, and 23-25 are pending in this application. The Examiner has rejected all of these claims. Claims 15, 18, 20, 21, and 23-25 as amended during prosecution are reproduced in the **Claims Appendix** attached hereto. Appellants are appealing the rejections of Claims 15, 18, 20, 21, and 23-25.

IV. STATUS OF AMENDMENTS

Appellants filed a Response on October 13, 2009 and a final Office Action was mailed on January 5, 2010. No claims were amended subsequent to the Examiner's final rejection that was mailed on January 5, 2010.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Independent Claim 25 describes a pharmaceutical composition for optical imaging for diagnosis of CRC, for follow up of progress of CRC development or for follow up of treatment of CRC, comprising:

(i) an optical imaging contrast agent with affinity for an abnormally expressed biological target associated with colorectal cancer (CRC), said contrast agent being of formula I:

V-L-R (I)

wherein:

V is one or more vector moieties having affinity for an abnormally expressed target in CRC, where said target is c-met, said vector moiety having a molecular weight below 4,500 Daltons;

L is a linker moiety or a bond, and

R is one or more reporter moieties detectable in optical imaging,

wherein the contrast agent has a molecular weight below 7,000 Daltons and a water solubility of at least 1mg/ml at pH 7.4;

(ii) at least one pharmaceutically acceptable carrier or excipient.

Support for claim 25 can be found on page 7, line 10 to page 8, line-30 of the specification.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The issues for review in this appeal arise from a Final Rejection that was mailed on January 5, 2010. The Examiner rejects claims 15-18, 20, 21, and 23-25 under 35 U.S.C. § 103(a) as being unpatentable over Marten *et al.* (Gastroenterol., 122, 406-414 (2002) ("Marten") in view of Klaveness *et al.* U.S. Patent No. 6,610,269B1) ("Klaveness") and in further view of Waggoner et al. U.S. Patent No. 6,008,373 ("Waggoner").

The Examiner also rejects claims 15-18, 20, 21, and 23-25 under 35 U.S.C. § 103(a) as being unpatentable over Weissleder *et al.* (Nature Biotech., 1999, 17, 375-378) ("Weissleder") in view of Klaveness and further in view of Waggoner.

Claims 15-18, 20, 21, and 23-24 are dependent on claim 25 and inherit all the limitations set forth in claim 25. Therefore, the issues in this appeal are:

1. Whether Marten or Weissleder in view of Klaveness and further in view of Waggoner disclose, teach, or suggest all the elements of claims 15-18, 20, 21, and 23-25?

VII. ARGUMENT

The Examiner rejects claims 15-18, 20, 21 and 23-25 under 35 U.S.C. § 103(a) as being unpatentable over Marten *et al.* (Gastroenterol., 122, 406-414 (2002) ("Marten") in view of Klaveness et al. U.S. Patent No. 6,610,269 B1) ("Klaveness") and in further view of Waggoner et al. U.S. Patent No. 6,008,373 ("Waggoner").

The Examiner also rejects claims 15-18, 20, 21, and 23-25 under 35 U.S.C. § 103(a) as being unpatentable over Weissleder et al. (Nature Biotech., 199, 17, 375-378) ("Weissleder") in view of Klaveness and further in view of Waggoner.

Appellants respectfully request that The Board of Patent Appeals and Interferences ("Board") should reverse the Examiner's rejections for the reasons set forth below.

A. The Examiner's Rejections of Claims 15-18, 20, 21, and 23-25 Should be Reversed Since Marten or Weissleder in view of Klaveness and further in view of Waggoner Fail to Teach All the Elements of the Claims

Claims 15-18, 20, 21 and 23-25 stand rejected as being obvious over Marten, in view of Klaveness and Waggoner. The Examiner's logic is that the person skilled in the art would be motivated to modify the cathepsin B NIR fluorochrome probes of Marten, by applying the teaching of Klaveness or Waggoner.

Appellants respectfully submit that it is impermissible within the framework of 35 U.S.C. §103 to pick and choose from any one reference only so much of it as will support a given position to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one skilled in the art. *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc.*, 796 F.2d 443 (Fed. Cir. 1986). (emphasis added).

Appellants point out that independent claim 25 is limited to c-Met as the biological target associated with the optical imaging of CRC. Marten, Klaveness and Waggoner do not disclose, teach, or suggest using c-Met. Hence, Appellants contend that no combination of those references could provide the subject matter of the present claims. In addition, as already acknowledged by the Examiner in an Office Action dated September 24, 2007, the logical combination of those references teaches towards probes which target a different biological target, i.e. cathepsin B. Thus, the combination teaches away from the subject matter of the present revised claims.

Therefore, the claims of the present invention cannot be merely assumed obvious

from the Examiner's subjective view point. Appellants note that "the prior art itself must provide a motivation or reason for the worker in the art, without the benefit of the Applicant's specification, to make necessary changes in the reference device". See, *Ex parte Chicago Rawhide Manufacturing Co.*, 226 U.S.P.Q. 438 (PTO Bd. App. 1984). It is well settled in the law that a reference must be considered not just for what it expressly teaches, but also for what it fairly suggests to one who is unaware of the claimed invention. *In re Baird*, 16 F.3d 380, (Fed. Cir. 1994).

Appellants therefore believe the obviousness rejection based on Weissleder, Klaveness and Waggoner should also be withdrawn.

Claims 15-18, 20, 21 and 23-25 also stand rejected as being obvious over Weissleder, in view of Klaveness and Waggoner. The Examiner's logic is that the person skilled in the art would be motivated to modify the protease activatable probes of Weissleder, by applying the teaching of Klaveness or Waggoner.

Appellants refer to Marten [Gastroenterol., 122, 408-414 (2002)], cited above where the same cathepsin B probe of Weissleder is described. Figure 1 (page 408), and the associated text makes it clear that the probe is activated by the enzyme action of cathepsin B.

Appellants therefore believe the obviousness rejection based on Weissleder, Klaveness and Waggoner should also be withdrawn.

CONCLUSION

In view of the foregoing, Appellants respectfully request that the Board reverse the rejections of Claims 15-18, 20, 21, and 23-25 as set forth in the Office Action mailed January 5, 2010, that the Board allow the pending claims since they are in condition for allowance, and that the Board grant any other relief as it deems proper.

Dated: June 7, 2010

Respectfully submitted,

/Craig M. Bohlken/
Craig M. Bohlken
Reg. No. 52,628
GE Healthcare, Inc.
101 Carnegie Center
Princeton, NJ 08540-6231
Phone No.: (609) 514-6530

VIII. CLAIMS APPENDIX

Claim 1-14 (Cancelled)

15. A contrast agent as defined in claim 25 wherein R is a cyanine dye.

16. A contrast agent as defined in claim 25 wherein the target is a receptor or a non-catalytical target.

17. A contrast agent as defined in claim 25 comprising a contrast agent substrate, wherein the target is an abnormally expressed enzyme, such that the contrast agent changes pharmacodynamic properties and/or pharmacokinetic properties upon a chemical modification from a contrast agent substrate to a contrast agent product upon a specific enzymatic transformation.

18. A contrast agent as claimed in claim 17 wherein the contrast agent changes binding properties to specific tissue, membrane penetration properties, protein binding or solubility properties upon the chemical modification.

19. (Cancelled)

20. A contrast agent as defined in claim 25 wherein V is selected from peptides, peptoid moieties, oligonucleotides, oligosaccharides, lipid-related compounds and traditional organic drug-like small molecules.

21. A contrast agent as claimed in claim 20 wherein V is a peptide.

22. (Cancelled)

23. A contrast agent as defined in claim 25 for the manufacture of a diagnostic agent for use in a method of optical imaging of CRC involving administration of said diagnostic agent to an animate subject and generation of an image of at least part of said subject.

24. A method of generating an optical image of an animate subject involving administering a contrast agent to the subject and generating an optical image of at least a part of the subject to which the contrast agent has distributed, characterized in that a contrast agent as defined in claim 25 is used.

25 A pharmaceutical composition for optical imaging for diagnosis of CRC, for follow up of progress of CRC development or for follow up of treatment of CRC, comprising:

(i) an optical imaging contrast agent with affinity for an abnormally expressed biological target associated with colorectal cancer (CRC), said contrast agent being of formula I:

V-L-R (I)

wherein:

V is one or more vector moieties having affinity for an abnormally expressed target in CRC, where said target is c-met, said vector moiety having a molecular weight below 4,500 Daltons;

L is a linker moiety or a bond, and

R is one or more reporter moieties detectable in optical imaging,

wherein the contrast agent has a molecular weight below 7,000 Daltons and a water solubility of at least 1mg/ml at pH 7.4;

(ii) at least one pharmaceutically acceptable carrier or excipient.

IX. EVIDENCE APPENDIX

Appellants hereby list the following journal articles/patents that the Examiner cites against the present invention. Appellants enclose the below referenced journal articles herein.

Marten *et al.* (Gastroenterol., 122, 406-414 (2002):

U.S. Patent No. 6,610,269B1) ("Klaveness")

U.S. Patent No. 6,008,373 ("Waggoner")

Weissleder *et al.* (Nature Biotech., 199, 17, 375-378)

This is the evidence relied upon by the Examiner for rejection of appealed Claims 15-18, 20, 21, and 23-25 in the Office Action dated January 5, 2010.

X. RELATED PROCEEDINGS APPENDIX

There are no other appeals or interferences related to the instant appeal.